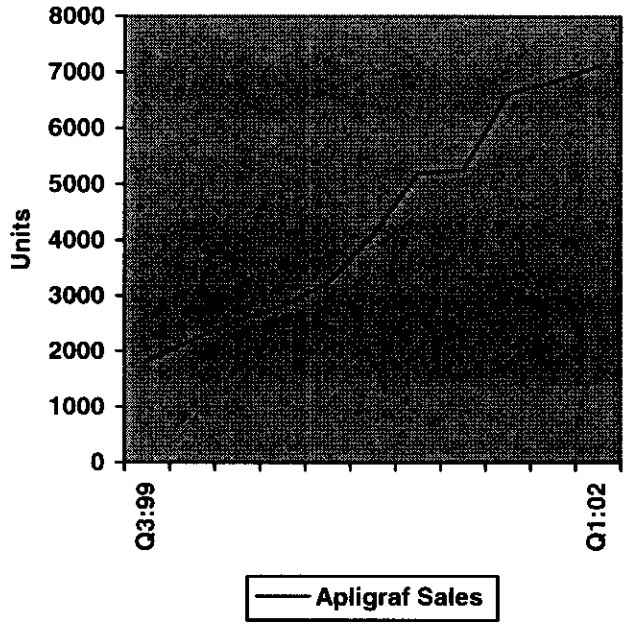
were wrong. There was, for example, nothing fraudulent about reporting on March 5, 2001 that "Apligraf sales are showing sustained growth acceleration," or that on September 6, 2001, there was "sustained strength in Apligraf sales." Stmts. 23, 33. Those announcements were completely justified in light of the improving sales:

Quarter	Apligraf Sales[10]
Q3 1999	1,817 units
Q4 1999	2,192 units
Q1 2000	2,555 units
Q2 2000	2,814 units
Q3 2000	3,232 units
Q4 2000	4,084 units
Q1 2001	5,194 units
Q2 2001	5,244 units
Q3 2001	6,606 units
Q4 2001	6,822 units
Q1 2002	7,102 units



All told, *sales increased almost 400% during the Class Period* -- and never decreased in any quarter. Plaintiffs come no closer to a real fraud claim with illusory challenges to the explanations for the sales growth. For example, plaintiffs cannot base a claim on the Company's announcement that the FDA approved Apligraf as a treatment for diabetic foot ulcers and that it qualified for Medicare reimbursement because the Complaint nowhere alleges that those milestones did not boost sales. See Stmt. 10 ("Key to Apligraf sales development are . . . approval for diabetic foot ulcers" and "reimbursement"); Stmt. 14 ("two important drivers of Apligraf sales: FDA approval for diabetic foot ulcers and Medicare reimbursement").

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[10] See Stmts. 29, 36; Press Release, April 3, 2002, App. Tab 43, p. 413.

Again unable to dispute the "hard" sales data that was reported, plaintiffs claim it was fraud for Organogenesis to have said it was "pleased" and "delighted" with those sales. Those adjectives were both warranted given the nearly 400% increase, and also puffery that is inactionable as a matter of law. Compare Stmts. 3, 19, 21, 29, 33, 36 (characterizing sales as "record" or "strong") with Greebel, 194 F.3d at 189, 207 ("sales continue to be strong" inactionable puffery); Compare Stmt. 21 ("*pleased* with the acceleration and sustained growth in Apligraf sales"), Stmt. 23 ("*pleased* with this acceleration"), Stmt. 33 ("*pleased*" with sales in "summer months"), and Stmt. 29 ("*delighted* with the growth in sales seen between June and July) with Greebel, 194 F.3d at 189, 207 (being "*pleased*" *not fraud*); Van Ormer, 145 F. Supp. 2d at 107 n.5 (being *"very pleased" not fraud*), and In re S1 Corp. Sec. Litig., 173 F. Supp. 2d 1334, 1349 n.10 (N.D. Ga. 2001) (being "*extremely pleased" not fraud*).

2. Defendants Never Misrepresented the Novartis Marketing Relationship

Throughout the Complaint, plaintiffs allege that Organogenesis misrepresented a business relationship whereby Novartis had exclusive rights to market Apligraf and the companies shared the revenue from sales. See Compl. 8, 60, 61, 64-66, 76, 87, 91, 100, 104, 108, 116, 119, 133, 145. Here plaintiffs complain that Novartis was incompetent and that the contract was disadvantageous because Organogenesis was "losing money on every unit." See Compl. 60, 61. These mismanagement claims fail for several reasons.

a) Defendants Are Not Liable Because Novartis Allegedly "Had No Idea" How to Market The "First and Only" Living Skin Product.

Plaintiffs claim that Novartis personnel "did not have the proper training, experience or expertise in marketing a living product" and "had no idea what they were doing when it came to marketing a living-tissue product like Apligraf." See Compl. ¶ 61(a), (b). As an initial matter, nowhere does the Complaint identify any statement by any defendant that Novartis had

experience with a living tissue product. See Fitzer, 119 F. Supp. 2d at 18 (complainant in securities fraud action must allege, among other things, a fraudulent statement). To the contrary, no reasonable investor could possibly have thought that Novartis (or anyone) had experience selling a "living-tissue product" because plaintiffs concede the market was told that Apligraf is "unique" and in fact was the "first and only product containing living human cells." See Compl. ¶¶ 2, 54, 146.

In any event, the "fact that a new product might face problems in the market is obvious to a reasonable investor, and therefore omission of it is not culpable." Boston Tech., 8 F. Supp. 2d at 62-63. Defendants did not conceal that ever-present risk of failure by stating that Novartis had a "marketing and sales force with technical expertise and distribution capability." See Stmt. 9. Novartis was and is one of the world's most experienced and successful pharmaceutical companies. Plaintiffs do not allege otherwise. No reasonable investor, however, would interpret Novartis' experience as a guarantee that the first and only living skin therapy would find success in the market. Plaintiffs' claim is particularly deficient because Organogenesis went ahead and disclosed the obvious risk that Novartis might fail:

> WE CURRENTLY DEPEND UPON NOVARTIS TO MARKET APLIGRAF AND NOVARTIS MAY NOT BE SUCCESSFUL IN MARKETING APLIGRAF IN THE FUTURE
>
> We currently have limited experience in sales, marketing and distribution and have developed a long-term strategic relationship with Novartis, who has marketing and sales forces with technical expertise and distribution capability. *Our revenues will depend upon the efforts of Novartis, who may or may not be successful in marketing and selling Apligraf* or gaining international approvals for the product.

10-K for 2000, Mar. 30, 2001, App. Tab 25, p. 212 (emphasis added).

Finally, plaintiffs do not plead with particularity that Novartis did, in fact, fail to market Apligraf effectively. Orton, 344 F. Supp. 2d at 298 (even if material, statement is actionable

only if its falsity is with requisite specificity). That sales increased consistently and dramatically flat-out contradicts plaintiffs' never-particularized theme that Novartis was so incompetent. Instead, plaintiffs blithely insist (nearly ten times) that Novartis had "no idea what they were doing" and that a purported lack of "training, experience or expertise . . . hindered Novartis' ability to sell Apligraf." See Compl. ¶¶ 61, 76, 87, 91, 100, 104, 116, 133, 145. Fatally absent, however, is Rule 9(b) and Reform Act specificity: *What* type of training did Novartis personnel have? *What* more training did they need? *When* and *how many* sales were lost as a result? See In re Peritus Software Servs., Inc. Sec. Litig., 52 F. Supp. 2d 211, 226 (D. Mass. 1999) (dismissing complaint where, as here, plaintiffs did not allege "the who, what, when, where, and how"). In fact, plaintiffs who allege that Novartis "hindered" sales do not allege a single instance of that happening. See Wenger v. Lumisys, Inc., 2 F. Supp. 2d 1231, 1247 (N.D. Cal. 1998) (Reform Act and Rule 9(b) not satisfied by "amorphous and conclusory allegations" of mismanagement where, as here, plaintiffs do not "quantify the ensuing" problem).[11] The securities laws do not provide a forum for plaintiffs to second-guess in hindsight the business decision to partner with Novartis. Just as in Fitzer, however disappointing allegedly "inexperienced and poorly-trained sales and service personnel" may be to investors, "poor management is a risk that every investor takes. Damages flowing therefrom are not actionable under the securities laws." See Fitzer, 119 F. Supp. 2d at 31.

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[11] Plaintiffs add nothing to the inadequate mismanagement allegations by attributing them to an anonymous "former director (non-Board level) on the senior management team of Organogenesis" who was employed in no particular time "during the Class Period." Compl. ¶ 61; See Gavish v. Revlon, No. 00 Civ. 7291 (SHS), 2004 WL 2210269 (S.D.N.Y. Sept. 30, 2004) ("affixing the phrase 'former employees have stated' to this otherwise totally unparticularized allegation does not transform it into an allegation that meets the particularity requirements of the PSLRA.").

b. Plaintiffs Cannot Sue Because of Apligraf was Unprofitable Under the Allegedly Adverse "Terms" Of The Novartis Contract.

Plaintiffs also cannot bootstrap mismanagement allegations into a fraud claim by complaining that Organogenesis was "losing money on every unit of Apligraf" because it negotiated a poor contract with Novartis. Compl. ¶¶ 8, 60, 65, 76, 87, 91, 100, 104, 116, 119, 133, 145. Nowhere does the Complaint allege that anyone claimed Apligraf was profitable. See In re Copley Pharm., Inc., Civ. A. No. 94-11897, 1995 WL 169215, at *2 n.5 (D. Mass. Mar. 16, 1995) (securities laws are about "actual statements, whether or not they are true or false, and, if false, whether or not the utterer knew at the time the statements were made that they were false"). To the contrary, defendants repeatedly disclosed to all investors that "production costs exceeded product sales" for Apligraf. (The prominently disclosed fact that Apligraf was unprofitable was, of course, the reason why Organogenesis reported increasing losses and negative cash flow for throughout the Class Period. See supra § II.A.).[12]

Plaintiffs also have never identified any material public statement that was rendered misleading by any other allegedly undisclosed "adverse" and/or "disadvantageous" terms of the Novartis contract. Compare Compl. ¶¶ 60, 65 with Serabian, 24 F.3d at 361 (to state fraud claim

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[12] Even if "poor contract" claims were actionable under the securities laws, plaintiffs do not plead the allegedly "adverse terms" of this one with Rule 9(b) and Reform Act particularity. How much revenue did Organogenesis receive per unit of Apligraf? How much more do plaintiffs think Novartis should have paid per unit for the deal to have been fair (as opposed to "disadvantageous")? What was the average cost to manufacture a unit of Apligraf? What was the marginal cost? And, ultimately, how much of Organogensis' business failure in 2002, and therefore plaintiffs' investment loss, is attributable to the "adverse terms" with Novartis (as opposed to other business issues or the fact that the overall market dropped and financing opportunities dried up following the September 11th terrorist attacks). See Romani v. Shearson Lehman Hutton, 929 F.2d 875, 880 (1st Cir. 1991) (dismissing securities fraud action where plaintiffs failed to allege "in some detail the facts and figures upon which their claims of misrepresentation were based"); Decker v. Massey-Ferguson, Ltd., 681 F.2d 111, 116 (2d Cir. 1982) (holding that allegation that company's failure to write down value of obsolete equipment does not sufficiently plead fraud where plaintiff did not allege amounts at which equipment was carried -- or should have been carried -- on company's books).

"plaintiffs must plead more than that defendants acted irresponsibly and unwisely").[13] Plaintiffs cannot claim that defendants hid the fact that the Company was not paid on "units of Apligraf that were manufactured . . . but that ultimately were not sold," Compl. ¶ 66, because the basis upon which the Company was paid by Novartis was disclosed during the entire Class Period, under both the original and amended License and Supply Agreement. See License and Supply Agreement, App. Tab 51; Amendment V to License and Supply Agreement, App. Tab 4.

3. Defendants Never Misrepresented The Ability To Manufacture Apligraf.

Plaintiffs challenge Organogenesis' March 2001 statement that Apligraf was "mass-produced" and that it "expect[ed] production volume to increase." See Stmt. 25; see also Stmts. 2, 6, 9, 11, 15, 18, 27, 32, 39. The claims rest on the bald assertion that "there was no way" Organogenesis could mass-produce Apligraf, see Compl. ¶¶ 62(a), which is meaningless because plaintiffs do not allege any particularized facts that Apligraf was not "mass-produced." See Loan v. FDIC, 717 F. Supp. 964, 967 (D. Mass. 1989) (plaintiff cannot "merely quote a statement and assert that it is untrue"). Plaintiffs cannot elevate their inadequate "no-way-to-mass-produce" sound bite into a particularized pleading by repeating it *a dozen* more times in the Complaint, which simply turns an inadequate allegation into a repetitive, inadequate allegation (and may explain why there is a 100-plus page complaint that fails to state a claim). See ¶¶ 76(b), 87(e), 87(g), 91(c), 91(d), 100(d), 100(g), 104(c), 116(c), 119(f), 133(e), and 145(f).

The "mass-production" claim also ignores that, according to the Complaint, Apligraf was being produced in 2001 at a rate of more than 40,000 units per year. See Compl. ¶ 136. Yet plaintiffs nowhere allege by how much that volume fell short. Nor do they allege that Organogenesis ever once lost any particular level of sales because it could not manufacture

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[13] It bears noting that plaintiffs do not dispute the accuracy of the only challenged representation concerning the terms of the Novartis contract -- Organogenesis' statement that it was entitled to an increased percentage of Apligraf revenue after the Novartis deal was amended in February 2001. See Stmts. 22-26.

Apligraf quickly enough to keep pace with demand. Thus, there is no pleaded basis to dispute that 40,000 units/year was not mass-production for the "first and only product containing living human cells." Compl. ¶ 146; see Orton, 344 F. Supp. 2d at 298 (even if statement material, plaintiffs must plead an adequate foundation of falsity).

Plaintiffs' allegations of inadequate quality assurance and product recalls similarly lack the factual detail necessary to survive. See Compl. ¶ 62. The Complaint never specifies the frequency of these problems, but only that they occurred "often" and/or "on more than one occasion" and/or "several times." See Compl. ¶ 62(a-b). They also do not allege the extent of the problem, such as what percentage of shipments needed to be recalled, nor *even state what year these problems supposedly occurred.*[14]

Because Organogenesis is never alleged to have told investors that its production process was error-free, plaintiffs cannot sue defendants because that process supposedly was imperfect in respects that plaintiffs cannot quantify as material to the business. See Tuchman v. DSC Communications Corp., 14 F.3d 1061, 1070 (5th Cir. 1994) (affirming dismissal of "complaint recit[ing] various episodes and acknowledgements of corporate mismanagement and failings of quality control" because "mismanagement does not, standing alone, give rise to a 10b-5 claim"). In any event, the open market didn't need to be told that problems sometimes arise when manufacturing a "revolutionary" medical therapy, see Compl. ¶ 49; supra § II.A., although Organogenesis specifically warned investors of that risk as well. See App. Tab 9, p. 86 (because

[14] Plaintiffs' failure to specify when these supposed problems occurred is particularly important, because they claim that "[p]rior to the inception of the Class Period . . . the Company was even forced to recall several lots of Apligraf," Compl. ¶ 47, and there is no pleaded basis to believe that plaintiffs' "sources" are referring to any different incidents.

Apligraf manufacturing process is "complex," there may be difficulty manufacturing enough "to satisfy the demands . . . and our results of operations will be hurt.").[15]

IV. DEFENDANTS HAD NO DUTY TO – AND DID NOT – PREDICT THE FUTURE.

A. Defendants Did Not Violate Any Duty To Disclose.

Plaintiffs cannot challenge the undisputedly true statements about Organogenesis' past and present financial and business performance on the theory that defendants failed to comment about the future or different aspects of the business. Specifically, "silence absent a duty to disclose is not misleading." Basic Inc. v. Levison, 485 U.S. 224, 239 n. 17 (1988); Shaw, 82 F.3d at 1202. Defendants' only duty is to disclose additional information if it is "needed so that what was revealed would not be 'so incomplete as to mislead.'" Gross, 93 F.3d at 992 (quoting Backman v. Polaroid Corp., 910 F.2d 10, 16 (1st Cir. 1990)(en banc)). For this reason the Company's accurate announcement of product revenue for Q1 2000, see Stmt. 11, did not require defendants to disclose that "future sales development prospects were hampered," Compl. ¶ 91(c), or "adverse factors affecting the Company's. . . future viability." Compl. ¶ 91(c). First Circuit courts have "consistently held" that "an affirmative true statement about past results does not give rise to a duty to comment on its current status." Gross, 93 F.3d at 994; see Boston Tech., 8 F. Supp. 2d at 54 ("issuer's having accurately reported past successes does not give rise to a duty to tell the public that at present its conditions or prospects are less positive").

The First Circuit has also been equally clear that "by revealing one fact" about a business, defendants did not have any duty to reveal other facts that "would be interesting, market-wise." Backman, 910 F.2d at 16. Thus, the statement that the Company's financials complied with

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[15] Plaintiffs' allegation about "frustrated and disappointed" physicians, see Compl. ¶62(c), suffers the same defects. Plaintiffs do not identify a singly unhappy physician, quantify the number of the unhappy physicians or plead that any material amount of sales were lost due to the unhappiness. See Compl. ¶ 62(c), (d). To the contrary, sales of Apligraf increased each quarter during the Class Period. See supra § III.B.1.

GAAP, see Stmts. 6, 11, 15, 18, 27, 32, 39, did not, as plaintiffs posit, require discussion of "adverse factors" related to marketing, manufacturing, or whatever other issues plaintiffs contend "would be interesting." See Compl. ¶¶ 76(g), 91(e), 100(i), 104(e), 119(g), 133(f), 145(g). Nor did Organogenesis' statements that it planned to expand manufacturing operations and increase production to meet anticipated demand, see Stmts. 2, 6, 9, 11, 15, 18, 25, 27, 28, 29, 31, 32, 34, 39, require a public discussion about the strengths and weaknesses of manufacturing capabilities. See Zouras v. Hallman, No. Civ. 03-240-SM, 2004 WL 2191034, at *9 (D. N.H. Sept. 30, 2004) (statement that shipments expected to climb steeply not rendered misleading by alleged production problems).

B. Plaintiffs Have Not Alleged An Actionable Projection.

Plaintiffs claim that defendants made "representations" about Organogenesis' future performance and market prospects, but have not pointed to a single projection that is actionable under First Circuit law. The Court of Appeals has made plain that predictions are actionable only if they are "promises about future performance" or "project specific numbers that the company will certainly attain." Suna v. Bailey Corp., 107 F.3d 64, 70 (1st Cir. 1997).

The Challenged Statements here fall far short of that standard. Plaintiffs cannot, for example, state a claim based on Statement 35, where the Company said it "look[s] forward to these products contributing to the overall profitability of the Company" because the "rule [is] that exaggerated, vague, or loosely optimistic statements about a company are not actionable under Rule 10b-5." Boston Tech., 8 F. Supp. 2d at 54. Nor was it a fraud for Mr. Laughlin to have stated in a February 2001 interview that "we are now targeting to pass through break even and reach profitability in the second quarter of next year — sorry, the third quarter of next year." Compare Stmt. 22 with In re Galileo Corp. S'holders Litig., 127 F. Supp. 2d 251, 267 (D. Mass. 2001) (statement of "substantial revenue goals" that company "*hoped* to achieve" inactionable as

a matter of law); Hillson Partners, 42 F.3d at 212 (statement that company was "*on target* toward achieving the most profitable year in its history" inactionable) (emphasis added); Colby v. Hologic, Inc., 817 F. Supp. 204, 211 (D. Mass. 1993) ("Prospects for long term growth are bright" inactionable). Similarly deficient are the challenges to Statements 2, 6, 9, and 25 ("[w]e expect Apligraf commercial sales to increase"), and Statements 2, 6, 9, 11, 15, 18, 27, 32, and 39 ("we expect production volume to increase and our margins to improve"), because these and other "vague predictions about the prospects for a new product . . . or for a company in general" are immaterial as a matter of law.[16] Boston Tech., 8 F. Supp. 2d at 54; see also Shaw, 82 F.3d at 1219 (statement that company "should show progress quarter over quarter, year over year" dismissed as puffery); San Leandro Emergency Med. Grp. v. Philip Morris Co., 75 F.3d 801, 807, 811 (2d Cir. 1996) (holding not actionable statement that company "expect[ed] ... another year of strong growth in earnings per share").

Of course, even if "optimism" and non-guaranteed "targets" could ever be actionable under First Circuit law (they are not), the statements that plaintiffs challenge were indisputably true. See Orton, 344 F. Supp. 2d at 299-303 (even if not puffery, statement not actionable if no factual basis for falsity). Most notably, plaintiffs cannot challenge any statement of expectation that Apligraf sales would improve (Stmts. 2, 6, 9, and 25) because by the end of the Class Period sales had in fact increased (by nearly 400%). See supra § III.B.1. Nor could any investor possibly have been defrauded by the statement that "[w]e expect production volume to increase and our margins to improve," because both did. See Compl. ¶ 136 (Apligraf production at rate of 40,000 units/year); ¶ 117 ("product margin improved significantly over last year").

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[16] Statement 4 is deficient because it is not even a statement. See Compl. ¶ 73. Instead, plaintiffs assert that, during a speech, Mr. Laughlin allegedly reiterated never-specified guidance and made the indisputably true statement that he considered Organogenesis to be operating according to plan. Id.

Likewise, plaintiffs cannot state a claim based on any supposed projection that the Company "would be able to achieve profitability in the foreseeable near-term." See Compl. ¶ 53. *Nowhere* does the Complaint identify any hard projection that would be actionable under Suna, Colby, Galileo, and other First Circuit precedent. The claim is particularly unfounded because the Company warned that, "[w]e have not achieved profitability and expect to continue to incur net losses. The extent of future losses and the time required to achieve profitability is highly uncertain." See Form 10-K for 1999, App. Tab 9, p. 83.

C. In The Alternative, The Forward-Looking Statements Are Protected By The Safe Harbor.

Even if plaintiffs had identified a statement about Organogenesis' future that was both sufficiently concrete to be deemed an actionable "projection" and that proved false (they have pleaded neither), they still would not state a claim because the Reform Act statutorily exempts the "forward-looking" statements from litigation. Specifically, the "safe harbor" provisions of the Reform Act require dismissal of challenges to forward-looking statements[17] identified as such and "accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement." See 15 U.S.C. §78u-5(c)(1)(A)(i)-(B); Baron v. Smith, 380 F.3d at 53-54 (affirming dismissal where "press release contained forward-looking statements, as so stated therein, and therefore comes under the protection of the statutory safe harbor"); In re Seachange Int'l, Inc. Sec. Litig., No. Civ.A. 02-12116-DPW, 2004 WL 240317, at *5-7 (D. Mass. Feb. 6, 2004) (dismissing challenges to statements as protected under the PSLRA safe harbor).

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[17] "Forward-looking" statements include projections of revenues, income and earnings, statements of management's plans and objectives for future operations (including plans or objectives relating to products), statements about future economic performance, and disclosure of the issuer's assumptions underlying the foregoing. See 15 U.S.C. §§ 77z-2(i)(1), 78u-5(i)(1).

There is no question that the Safe Harbor forecloses plaintiffs' challenge to the statements about Organogenesis' future. The Company's SEC filings disclosed that they included forward-looking statements and referred investors to various risk factors described in the SEC filings. See, e.g., Form 10-K for 1999, App. Tab 9, pp. 80, 83-89 (extensive safe harbor disclosures). For example, even if defendants had made a worded-as-a-guarantee projection of Organogenesis' ability to stay solvent, the Company was explicit that numerous factors could "adversely impact our capital resources" in the future, and that:

> There can be no assurances that these funds will be available when required on terms acceptable to us, if at all. If adequate funds are not available when needed, we would need to delay, scale back or eliminate certain research and development programs or license to third parties certain products or technologies that we would otherwise undertake ourselves, resulting in a potential material adverse effect on our financial condition and results of operations.

See id. p. 89; Compare In re U.S. Interactive, Inc., No. 01-CV-522, 2002 WL 1971252, at *9 (E.D. Pa. Aug. 23, 2002) ("statement about USIT's ability to remain solvent is a financial projection that falls squarely within the statutory definition of a forward-looking statement;" accompanying cautionary language was sufficient to warn investors that it was not guaranteed that USIT would be solvent for a period of 18 months).[18]

V. AN ALLEGED "LACK OF LEADERSHIP" WASN'T FRAUD.

Plaintiffs assert additional mismanagement allegations of corporate "infighting" and that there were "too many presidents, and too many going in different directions -- a lack of leadership." See ¶ 63. "A claim of fraud cannot arise from poor management," Fitzer, 119 F.

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[18] Organogenesis also warned of the other risks that plaintiffs complain about, such as the risk that doctors would not like Apligraf, see App. Tab 9, p. 83 ("Our business results would be hurt if we are unable to demonstrate to the medical community the efficacy, relative safety and cost effectiveness of treating patients with our products or if our products were not accepted as alternatives to other existing or new therapies"), and that Novartis might be unsuccessful in marketing the product. See id. p.84 ("We are dependent on Novartis for the successful marketing and selling of Apligraf worldwide. If Novartis does not succeed in marketing and selling Apligraf or gaining international approvals for the product or if we are unable to meet the production demand of global commercialization, our operating results will suffer.").

Supp. 2d at 33, (citing Santa Fe Indus. Inc. v. Green, 430 U.S. 462, 479 (1977)), or high management turnover. Plaintiffs cannot dispute that Organogenesis disclosed changes in senior management in the public filings and press releases. See, e.g., Compl. ¶¶ 122, 147. Having so disclosed, Organogenesis had no obligation to state the obvious that management turnover can be disruptive. See Craftmatic Sec. Litig. v. Kraftsow, 890 F.2d 628, 640 (3d Cir. 1990) (no liability under securities laws for "failure to disclose" managerial "incompetence"); Berger v. Beletic, 248 F. Supp. 2d 597, 604 (N.D. Tex. 2003) (no duty to disclose "obvious possibilities").

Moreover, the Complaint does not allege that Company operations were disrupted in any particular way or give a single example of any "infighting." See In re Vantive Corp. Sec. Lit., 283 F.3d 1079, 1086-87 (9th Cir. 2002) (dismissing allegations that company "was suffering serious problems" with management who "were distracted" and "unable to effectively manage" because of "continual disagreements and in-fighting" where, as here, complaint did not indicate "what the 'continual' disagreements that supposedly 'plagued' the managerial team consisted of").

VI. PLAINTIFFS DO NOT STATE A CLAIM BASED ON THE "CONFIDENTIAL ARCARI DOCUMENT."

The Complaint is peppered with allegations attributed to the so-called "Confidential Arcari Document." Plaintiffs claim the document was authored by John Arcari in October 2001 and states that at no time in particular, Albert Erani "sought" to have never-identified stock brokers "manipulate the market for the Company's stock," "encouraged the Company to prepare overly optimistic financial projections" for never-identified "existing and potential service providers" and engaged in other misconduct. See Compl. ¶ 7.

Plaintiffs cannot avoid dismissal with these inflammatory allegations. They nowhere allege that *any* of the other six defendants ever saw the document, ever knew it existed, or in any

other way was involved in the document or the non-specific misconduct for which it is cited. It is therefore irrelevant to the claims brought against Ms. Lopolito, Mr. Tuck, Mr. Laughlin, Mr. Sabolinski, Mr. Ades and Mr. Stein.[19]

VII. PLAINTIFFS FAIL TO PLEAD SCIENTER.

Fraudulent intent is the essence of any fraud claim. For this reason the "most salient feature" of the Reform Act is the high pleading bar for scienter. See Greebel, 194 F.3d at 196 (construing 15 U.S.C. § 78u-4(b)(2)). To state a claim, plaintiffs must "state with particularity facts giving rise to a strong inference" that *each* defendant acted with scienter "with respect to *each* [alleged] act or omission." 15 U.S.C. § 78u-4(b)(2); Greebel, 194 F.3d at 195-198. Plaintiffs fail to do so here, because they fail to plead facts demonstrating that any defendant was aware of the "adverse facts" that allegedly render the Challenged Statements misleading, and their "motive and opportunity" allegations are insufficient to infer an intent to deceive on the part of any defendant.

A. Plaintiffs Have Failed to Allege Conscious Wrongdoing.

Plaintiffs fail entirely to plead "classic" scienter, i.e., a factual basis to support a strong inference that each defendant made statements "when [he or she] knew facts suggesting the statements were inaccurate or misleadingly incomplete." Cf. Aldridge v. A.T. Cross Corp., 284 F.3d 72, 83 (1st Cir. 2002). For starters, plaintiffs' failure to particularize the link between defendants and the Challenged Statements, see supra § I., necessarily forecloses any strong (or any) inference that defendants set out to deceive investors via the statements they didn't make. Karacand v. Edwards, 53 F. Supp. 2d 1236, 1252 (D. Utah 1999) (where plaintiffs failed to plead

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[19] Even as to Messrs. Erani and Arcari, the document could not possibly support plaintiffs' claims. The document was allegedly authored in October 2001 – *after* 35 of the 39 Challenged Statements had been made. Nor does the "confidential" document state a claim as to Statements 36-39. See Exhibits C, D.

false statements, "*a fortiori* they have not established that defendants knew those statements were false") (citation omitted).

Moreover, plaintiffs have failed to plead scienter even in the precious few circumstances where they have identified a particular individual (as opposed to "all" defendants) as the author/speaker of a Challenged Statement. The Complaint does not "point to facts" demonstrating that "at the time the statements were made" the identified individual knew the negative information that he or she allegedly suppressed. See Carney, 135 F. Supp. 2d at 244.[20]

Instead of specificity, plaintiffs assert that all eight undifferentiated "defendants" had access to "adverse undisclosed information" via "internal corporate documents," "conversations," "attendance at . . . meetings" and from whatever "other information [was] provided to them." See Compl. ¶ 34. This is the same conclusory boilerplate that First Circuit courts routinely reject. See Carney, 135 F. Supp. 2d at 255 (finding no strong inference of scienter derived from "unspecified plans, budgets, forecasts, reports, conversations, connections, meetings and 'other' information to which . . . defendants had access because of their positions"). Fatally absent from the Complaint is any specification of the "internal reports" or "conversations" that plaintiffs speculate each individual was privy to, much less the content and whether the individual received the information at the time of the 39 Challenged Statements. See Shaw, 83 F.3d at 1224 n. 38 (no "factual basis for inferring any such knowledge" from similarly generic allegations that "highly-efficient reporting system" provided information to management "absent some indication of the specific factual content of any single report generated by the

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[20] For example, Plaintiffs assert that defendants were aware that Novartis' marketing team was incapable of marketing Apligraf, yet they *do not identify a single instance where any defendant received a complaint about Novartis, expressed dissatisfaction with Novartis or learned that Novartis fell short of its sales projections.* Plaintiffs also assert that defendants knew they could not achieve profitability because of the terms of the Novartis marketing agreement, *yet fail to identify a single financial document prepared or reviewed by any defendant.* Similarly, plaintiffs assert that defendants knew their manufacturing process was deficient, *but fail to identify a single internal report regarding production goals or actual production.* Absent such factual allegations, there is simply no basis for the Court to infer that any defendant knew the allegedly undisclosed "adverse facts."

alleged reporting system"); Boston Tech., 8 F. Supp. 2d at 57 (to base scienter on "internal reports, memoranda or the like," plaintiffs typically identify the reports and "allege both the content of those documents and defendants' possession of them at the relevant time").

Plaintiffs' scienter allegations ultimately distill to never-acceptable status pleading. Plaintiffs cannot assume that all defendants knew about all the allegedly adverse facts simply by virtue of their job titles ("[b]oard membership and/or executive and managerial positions") or other "associations with the Company." Compare Compl. ¶¶ 37, 187 with Maldonado v. Dominguez, 137 F.3d 1, 10 (1st Cir. 1998) (rejecting allegations that defendants must have been aware of facts by virtue of their positions); In re Galileo, 127 F. Supp.2d at 261 ("Nor is scienter pleaded sufficiently by an allegation that . . . defendants must have known facts solely by virtue of their positions with the issuer of the securities").[21]

B. Plaintiffs Plead No Cognizable "Motive" For Fraud.

Plaintiffs cannot overcome their failure to plead conscious wrongdoing by asserting that defendants were "motivated" to conceal the Company's "true operational and financial condition." Compl. ¶ 9. That theory could not amount to scienter because, even if it were well pleaded, "merely pleading motive and opportunity . . . is not enough." See Greebel, 194 F.3d at 197; Lirette v. Shiva Corp., 27 F. Supp. 2d 268, 281 (D. Mass. 1998) (same).

The "motive and opportunity" allegations should be disregarded entirely. For the most part, plaintiffs simply plead pejoratives – such as the comments attributed to an anonymous former employee who thought that unnamed senior managers were "taking care of themselves at

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[21] For the same reason, plaintiffs have not pleaded fraud by insisting that, according to an anonymous "former Maintenance Supervisor for Organogenesis during the Class Period," the Company's problems with Novartis were "known by the whole company" – at an unspecified time during the two-plus year Class Period. See Compl. ¶ 65. This only spotlights plaintiffs' failure to plead anything supporting a strong inference of knowledge as to any individual defendant. See Fitzer, 119 F. Supp. 2d at 25 (refusing to "speculate" that "because former employees in the corporation knew of [adverse facts], the corporate executives must also have known").

the top" because of "corporate greed." See Compl. ¶ 67. These ad hominem attacks are even weaker than the generic "catch-all allegations that defendants stood to benefit from wrongdoing" that First Circuit courts always reject. See Greebel, 194 F.3d at 197 (citation omitted); Carney, 135 F. Supp. 2d at 256 (dismissing "*pleading fallacy*" that defendants were motivated to inflate stock price where no "specific facts" connected that generic motive to challenged statements) (emphasis added).

Finally, plaintiffs fail in their attempt to plead scienter through insider trading. The Complaint does not allege that defendants' sales were "unusual, well beyond the normal patterns of trading by [the] defendants." See Greebel, 194 F.3d at 198, 206 (insider trading insufficient to establish scienter even where, unlike here, defendants sold millions of dollars of stock because trading activity not suspicious). Plaintiffs begin their Complaint with the sinister-sounding allegation (in bold and italics) that "insiders" and "certain defendants" were motivated to commit fraud to "register for sale and/or sell" securities "valued at over $68 million." See Compl. ¶ 9. That allegation is, at best, disingenuous -- because it is not until 101 pages later that plaintiffs clarify that ***six of the individuals defendants did not sell a single share during the Class Period (Messrs. Ades, Erani, Laughlin, Arcari, Tuck and Ms. Lopolito).*** Compare Compl. ¶¶ 188-189 with In re Ciena Corp. Sec. Litig., 99 F. Supp. 2d 650, 662 (D. Md. 2000) (dismissing individual defendant who, like these, "did not sell a single share of his stock during the Class Period. Thus, his motive could not have been to inflate the value of [the company's] stock . . .").

Plaintiffs also bury at the end of the Complaint the fact that the vast majority of the supposedly nefarious insider trading ($61 million, or more than 90%) was not insider trading at all -- but instead were the fully-disclosed stock sales by Organogenesis. See Compl. ¶¶ 188-89. Courts consistently reject plaintiffs' theory that a company's need for financing "evidences" the

individual defendants' supposed "motive to perpetrate the fraud[]." Compare Compl. ¶ 189 with Meyer v. Biopure Corp., 221 F. Supp. 2d 195, 209 (D. Mass. 2002) (defendant's attempt to secure financing to continue operations not sufficient "to create a blanket presumption that any omissions were made with intent to defraud"); McNamara v. Bre-X Minerals, Ltd., 57 F. Supp. 2d 396, 405 (E.D. Tex. 1999) (stating that motive to commit fraud cannot be proven by allegations that a defendant acted to improve company's financial health or increase capital).[22]

Thus, plaintiffs' theory that all defendants committed a fraud "to get back their investments," see Compl. ¶ 67, collapses under the fact that the *only* individual defendants alleged to have sold stock during the Class Period are Mr. Stein (who apparently sold 700,000 shares at a *loss*) and Dr. Sabolinski ($126,841). See Compl. ¶ 188. Dr. Sabolinski's trading is hardly "unusual" -- he exercised only a tiny fraction (3.3%) of his stock options. Compl. ¶ 188; Form 4, July 7, 2000, App. Tab 45, p. 441 (showing Dr. Sabolinski holding 369,958 options after exercise of 12,208). (Mr. Stein's trading also is not actionable for the reasons set forth by the separate brief submitted by his counsel.)[23]

If anything, the fact that for a two year period there was virtually no trading by Organogenesis' officers and directors (which is unusually minimal trading for a public company) undercuts any inference of fraud. See, e.g., In re e.Spire Communications Inc. Sec. Litig., 127 F. Supp. 2d 734, 744 n.9 (D. Mass. 2001) (fact that CFO did not sell stock during Class Period weakens scienter argument). Indeed, the notion that defendants were acting out of "greed" to

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[22] Such a "motive" to raise money is far too generic because it could be imputed to officials of any public company. See Glickman v. Alexander & Alexander Svcs., No. 93 Civ. 7594 (LAP), 1996 WL 88570, *6 (S.D.N.Y. Feb. 29, 1996) ("I cannot think of [a] broader . . . motive[] than 'a desire to raise much needed capital' for the benefit of the institutional defendant"); Novak v. Kasaks, 216 F.3d 300, 307 (2d Cir. 2000) ("plaintiffs could not proceed based on motives possessed by virtually all corporate insiders, including . . . the appearance of corporate profitability").

[23] Plaintiffs also allege inside trading by an individual *whom they did not even sue* (Parenteu). See Compl. ¶ 188. The allegation serves no purpose other than to increase the amount of stock sales that plaintiffs then improperly blame on the defendants.

"get back" their investment defies logic because, having not sold, the individual defendants lost far more than named plaintiffs - with Mr. Erani losing his investment in 1,408,475 shares (valued at as much as $31.5 million during the Class Period) and Dr. Sabolinski losing the opportunity to exercise options on 433,708 shares (or $9 million). See Compl. ¶ 81 (shares rallied to Class Period high of over $22.37 per share); Form 14A, May 24, 2001, App. Tab 41, pp.381-82 (listing shares of common stock beneficially owned as of April 20, 2001). That these defendants maintained these holdings throughout the Company's eventual demise is wholly inconsistent with plaintiffs' allegations that they were motivated to commit fraud by the prospect of personal gain.

VIII. PLAINTIFFS FAIL TO STATE A CLAIM FOR "CONTROL PERSON" LIABILITY.

The Court also should dismiss the "control person" claim under § 20(a) of the Exchange Act (Count II) for two reasons. First, plaintiffs "have failed to allege an underlying violation" of § 10(b), which is a prerequisite to any "control person" claim. See Suna, 107 F.3d at 72.

Second, this claim must be dismissed because plaintiffs do not allege that any defendant "actually exercised control over" any other defendant. See Aldridge, 284 F.3d at 85. The First Circuit requires plaintiffs to plead a significantly probative factual basis that the defendant did, in fact, "actually exercise control over" a primary violator, such that it would be appropriate to hold that defendant jointly and severally liable under § 20(a). See id. (citing Sheinkopf v. Stone, 927 F.2d 1259, 1270 (1st Cir. 1991) (§20(a) requires "significantly probative evidence" that the control person "exercised, directly or indirectly, meaningful hegemony" over primary violator")). Plaintiffs must do so with Rule 9(b) particularity. See Wells v. Monarch Capital Corp., No. 91-10575-MA, 1991 WL 354938, at *10 (D. Mass. Aug. 23, 1991).

Here, plaintiffs have not even attempted to allege that any defendant controlled any other named defendant. Instead, plaintiffs' "control person" claim rests entirely on the individual

defendants' alleged control of Organogenesis (the company) and not the other individuals. See Compl. ¶ 205. As plaintiffs have not pled a primary violation by Organogenesis (it is not even a defendant), *a fortiori* the individual defendants could not be jointly and severally liable for controlling the not-alleged primary violation by Organogenesis. See Griffin v. PaineWebber Inc., 84 F. Supp. 2d 508, 516 (S.D.N.Y. 2000) (control person claim dismissed where, as here, defendant allegedly controlled company that was not named as defendant because of bankruptcy); Picard Chemical Inc. Profit Sharing Plan v. Perrigo Co., 940 F. Supp. 1101, 1135 (W.D. Mich. 1996) (dismissing control person claim; "Plaintiffs cannot maintain an action by alleging control over members of the syndicate who were not named in the complaint and who will never be found liable for primary violations of the securities laws").[24]

[24] In addition, plaintiffs' "control person" claim suffers from the same deficiency as their §10(b) claim – many defendants were only in a position to "control" anything having to do with Organogenesis for small portions of the putative Class Period.

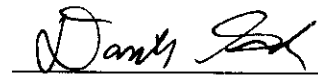
Conclusion

For the reasons set forth above, the Corrected Amended Consolidated Class Action Complaint should be dismissed with prejudice.

Respectfully Submitted,

ALAN ADES
JOHN J. ARCARI
ALBERT ERANI
PHILIP LAUGHLIN
DONNA ABELLI LOPOLITO
MICHAEL SABOLINSKI
ALAN W. TUCK

By their attorneys,



Jeffrey B. Rudman (BBO #433380)
Jonathan A. Shapiro (BBO #567838)
Daniel H. Gold (BBO #654909)
Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, Massachusetts 02109
(617) 526-6000
(617) 526-5000 (facsimile)

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